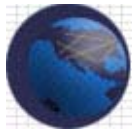


Clinical Trial Management Systems Teleconference

Date, Time & Location:	May 11, 2004; 12:00 EDT; Teleconference		
Attendees:	Center	Attendee	
	CARRA	Diane Paul	
	City of Hope	Joyce Niland Doug Stahl	
	CTEP	Beverly Meadows Anne Tompkins	
	Duke	Pearl Seo	
	First Genetic Trust	Aris Floratos	
	Georgetown University	Jieping Li	
	Karmanos Cancer Institute	Richard Pense Richard Rauscher	
	Mayo Clinic	Sharon Elcombe	
	Memorial Sloan Kettering	John Speakman	
	Oregon Health Sciences University	Lara Fournier	
	Terrapin Systems	Craig Fee Lily Liu Tushar Maiti	
	UC-Irvine	Andrea Hwang	
	UCSF	Terry Melese Diane Paul	
	University of Colorado	Jessica Bondy	
	University of Iowa	Terry Braun	
	University of Minnesota	Don Connelly	
	University of Pittsburgh	Mike Becich Doug Fridsma Valerie Monaco	
	Vanderbilt University	Sorena Nadaf	
	VA	Dave Rose	
	Wake Forest University	Steve Price Bob Morrell Todd Thornburg	
	NCI	Ken Buetow Sue Dubman Peter Covitz Christo Andonyadis Kathleen Gundry Joe Barry	
	BAH	Chalk Dawson Davis Bu Christine Richardson Mike Keller	
CDE Governance Model	<ul style="list-style-type: none"> • Vocabulary and Common Data Elements (VCDE) Working Group has discussed possible governance models for CDE curation within caBIG • Recommended Governance Model <ul style="list-style-type: none"> ○ Concepts originate from the Domain Workspaces ○ Formalization of these concepts would occur at the WS level, via a centralized group within the Domain Workspace ○ This group would be supported by the Vocabulary and Common Data Elements Working Group ○ The VCDE Working Group is responsible for the ultimate review/harmonization of the CDE in the caBIG context • Requires each Domain Working Group to assign responsibility for capturing and administering domain CDEs 		



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	<ul style="list-style-type: none">• The VCDE Working Group evaluated other alternatives before recommending the above model• Existing body of CDEs has been created to capture many data elements required in cancer research• In addition to reuse of existing CDEs, new CDEs will be created as new science needs are uncovered by ongoing caBIG projects• Process includes:<ul style="list-style-type: none">◦ Identifying required CDEs◦ Identifying existing CDEs that can be reused◦ Defining and proposing new CDE creation◦ Review of proposal by caBIG CDE governance structure• CDEs may be marked as provisional to allow continued application development during the CDE review process• A caBIG Context has been created, but any group can use CDEs from other Contexts• A number of external standards, such as SNOWMED, LOINC and HL7, are being reviewed by the VCDE Working Group for incorporation• For future information, please post questions and comments to the Forum, and note the schedule of upcoming webcasts on the caBIG website.
Contracts Update:	<ul style="list-style-type: none">• The General Contractor has contacted 30 centers with regards to the Master Contract, and Jackson Labs is close to signing• Discussions with many centers, such as Mayo, Irvine, Hutch and Jackson Labs, have been very helpful in re-working the contract language dealing with insurance, for hire, etc.• SOWs are being drafted in parallel to Master Contract Negotiations• Many Centers expressed interest in adopting a caBIG compliant data capture and management solution, and SOWs to adopt C3D are being drafted to meet this need• Regarding new SOW generation: After the SOW is drafted by the General Contractor and approved by the NCI, SOW negotiations include open discussions with the centers to ensure a common understanding of the work
CTMS Facts Sheet	<ul style="list-style-type: none">• Intended to summarize information gathered from the Workspace to date and provide a starting point for activities moving forward• Please send comments to Davis Bu for consolidation
Communications Infrastructure	<ul style="list-style-type: none">• Agreed to establish Special Interest Groups (SIG) for specific areas, including:<ul style="list-style-type: none">◦ CTMS/CDUS reporting◦ Financial Billing◦ Lab interfaces◦ Adverse Event Reporting◦ CDE group• Please notify Davis Bu by email of interest in participating in any SIG• caBIG participants should check the Forum and website frequently for

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	<p>updated information</p> <ul style="list-style-type: none"> • Agreement was reached that a point of contact list for the Working Group should contain names and email addresses for participants, and should be distributed by email rather than by public posting • Review process for meeting notes under review, but will include drafting by the General Contractor and review by the NCI and the Working Group to be completed in advance of the following meeting 			
Next Teleconference	<ul style="list-style-type: none"> • Next meeting: May 25, 12:00-1:00 EDT • Future teleconference to occur regularly on the 2nd and 4th Tuesday of every month, from 12:00-1:00 ET 			
Action Items:	Name Responsible	Action Item	Date Due	Notes
	Davis Bu	E-mail list of SIGs to WS	5/13/2004	
	Davis Bu	E-mail POC list	5/13/2004	
	All Participants	Review Facts Sheet and send comments to Davis Bu	5/18/2004	
	All Participants	Notify Davis Bu regarding interest in SIGs	5/18/2004	

Please list below and attach Meeting Materials and Agenda (if prepared separately):